IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

MERIAL LIMITED and MERIAL SAS, *

Plaintiffs, *

vs. *

CASE NO. 3:12-CV-75 (CDL)

VELCERA INC. and FIDOPHARM INC., *

Defendants. *

O R D E R

This Order constitutes the latest chapter in the intellectual property saga that may ultimately conclude with a determination of who has the legal right to an apparently magical formulation for ridding our dogs and cats of fleas and ticks. Plaintiffs Merial Limited and Merial SAS (collectively "Merial") manufacture and sell a product known as Frontline Plus pursuant to U.S. Patent No. 6,096,329 ("the '329 Patent"). Frontline Plus, which is touted as the best-selling veterinary product in the world, is a parasiticide for dogs and cats containing the active ingredients fipronil and methoprene. Defendants Velcera Inc. and FidoPharm Inc. (collectively "Velcera") have been working feverishly to develop and sell a generic version of Frontline Plus known as PetArmor Plus. Velcera's first version of PetArmor Plus ("2011 PetArmor Plus") had the exact same combination of active ingredients and the

same type of inactive ingredients that exist in Frontline Plus. In a previous contempt proceeding, the Court enjoined Velcera from selling that version of PetArmor Plus. After the Court issued that order, Velcera made a minor amendment to the inactive ingredients, and it now seeks to sell that slightly modified product ("2012 PetArmor Plus") in the United States.[1] Merial has filed this patent infringement action claiming that 2012 PetArmor Plus violates its '329 Patent. Velcera responds that the '329 Patent is invalid under 35 U.S.C. §§ 112 and 103(a), and that even if it is valid, the sale of 2012 PetArmor Plus will not infringe the patent.

Presently pending before the Court is Merial's Motion for Preliminary Injunction (ECF No. 5). Although Merial maintains that 2012 PetArmor Plus violates several claims of the '329 Patent, the resolution of the pending motion depends primarily on one key component of the patent, a requirement that the active ingredients, fipronil and methoprene, be present in "synergistic effective amounts." Based on the following findings of fact and conclusions of law, the Court grants Merial's motion.

[1]Specifically, Velcera intends to sell PetArmor Plus for Cats and PetArmor Plus for Dogs, both of which are veterinary spot-on treatments used to control fleas and ticks. The current versions of these products, which Merial claims infringe its patent, will be referred to as 2012 PetArmor Plus. The 2011 versions will be referred to collectively as 2011 PetArmor Plus.

FACTUAL AND PROCEDURAL BACKGROUND

The '329 Patent is assigned to Merial SAS, which granted Merial Limited an exclusive license to the patent. The '329 Patent claims topically applied ("spot-on") compositions for protecting domestic dogs and cats from fleas and ticks. Specifically, the '329 Patent claims spot-on compositions containing synergistic effective amounts of the pesticide fipronil and an insect growth regulator that prevents immature parasites from reaching reproductive maturity, as well as at least one customary spot-on formulation adjuvant. The '329 Patent discloses a number of insect growth regulators, including methoprene.[2] Merial asserts that in the fipronil plus methoprene compositions disclosed in the '329 Patent, the two active ingredients are present in synergistic effective amounts. In other words, Merial asserts that fipronil and methoprene are present in amounts sufficient to yield synergistic effects, meaning that the combination achieves improved results relative to either agent administered alone. The spot-on composition disclosed in the '329 Patent is intended to be applied to the skin of the dog or cat, usually to the neck or between the shoulder blades. The active ingredients move across the body of

[2] For purposes of this Order, references to methoprene include S-methoprene.

the animal and become concentrated in the animal's sebaceous glands, which are small oil-producing glands in the skin.

Merial markets compositions that combine fipronil and methoprene under the brand name Frontline Plus. Frontline Plus is the leading veterinary flea and tick treatment in the United States. Frontline Plus for Cats contains 9.8% fipronil and 11.8% methoprene, and Frontline Plus for Dogs contains 9.8% fipronil and 8.8% methoprene.

Velcera intends to sell two new veterinary products in the United States: LC-2010-3 Fipronil and S-Methoprene for Cats (PetArmor Plus for Cats) and LC-2010-4 Fipronil and S-Methoprene for Dogs (PetArmor Plus for Dogs). Each 2012 PetArmor Plus product has the exact same active ingredient formulation as the corresponding Frontline Plus product. Like Frontline Plus for Cats, 2012 PetArmor Plus for Cats contains 9.8% fipronil and 11.8% methoprene. And like Frontline Plus for Dogs, 2012 PetArmor Plus for Dogs contains 9.8% fipronil and 8.8% methoprene.

Velcera previously launched a product called PetArmor Plus in 2011, which it had developed in concert with Cipla Limited ("Cipla"). Prior to the launch of that product, Merial had obtained a default judgment against Cipla in an action in which Merial alleged that a Cipla fipronil/methoprene product, Protektor Plus, infringed Merial's '329 Patent. As a result of

that default judgment, Cipla and anyone acting in concert with Cipla was enjoined from, among other things, manufacturing or selling any product that infringed the '329 Patent. After the issuance of that injunction, Cipla and Velcera jointly developed and began selling 2011 PetArmor Plus. Upon learning of that allegedly infringing activity, Merial filed a contempt motion against Cipla for violating the previous injunction. Velcera intervened in that action to protect its interests regarding 2011 PetArmor Plus. After a hearing, the Court concluded that Velcera acted in concert with Cipla to violate the injunction by selling 2011 PetArmor Plus, and the Court found that the 2011 PetArmor Plus products infringed at least one claim of the '329 Patent. The Court entered an injunction against Velcera prohibiting Velcera from selling a veterinary product containing fipronil and methoprene if Cipla participated in the development, manufacture and/or packaging of the product. *Merial Ltd. v. Cipla Ltd.*, No. 3:07-CV-125 (CDL), 2011 WL 2489753, at *17 (M.D. Ga. June 21, 2011) [hereinafter *2011 Contempt Order*]. The Court's decision was affirmed on appeal to the Federal Circuit. *Merial Ltd. v. Cipla Ltd.*, Nos. 2011-1471, 2011-1472, 2012 WL 1948879 (Fed. Cir. May 31, 2012) [hereinafter *Fed. Cir. Op.*].

After this Court's contempt finding, Velcera severed ties with Cipla and reformulated the PetArmor Plus product with a

minor formula amendment. Specifically, Velcera eliminated two inert ingredients, the crystallization inhibitors, and replaced their lost volume by increasing the amount of an existing inert ingredient that acted as a solvent. Based on the similarities between the reformulated 2012 PetArmor Plus and the previously enjoined 2011 PetArmor Plus, Merial filed a contempt motion against Velcera, arguing Velcera's proposed launch of the reformulated product violated the injunction entered against Velcera. After an evidentiary hearing, the Court denied Merial's motion, finding Merial failed to meet its burden of proving by clear and convincing evidence that Cipla participated in the development of 2012 PetArmor Plus, which was a condition of the Court's injunction against Velcera. *See BASF AGRO B.V. v. Cipla, Ltd.*, No. 3:07-CV-125 (CDL), 2012 WL 2023310, at *1, *5 (M.D. Ga. June 5, 2012) (finding that the injunction prohibited "Velcera from selling (1) a veterinary product in the United States that (2) contains fipronil and methoprene if (3) Cipla participated in the development, manufacture and/or packaging of the product" and concluding that Merial failed to prove that Cipla participated in the development of the product by clear and convincing evidence). Merial responded by filing the present action to prevent the sale of 2012 PetArmor Plus, contending that the product infringes at least one claim of Merial's '329 Patent. At the present time, Merial seeks

preliminary injunctive relief until its claims can be finally adjudicated.

DISCUSSION

The Court held an evidentiary hearing on Merial's Motion for Preliminary Injunction. Based on the testimony and evidence received at that hearing, the Court makes the following findings of fact and conclusions of law.[3]

I. Preliminary Injunction Standard

"'A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.'" *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1323 (Fed. Cir. 2012) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The Court addresses each factor in turn.

[3] The Court heard live testimony and received exhibits on June 21-22, 2012. The Court also admitted the declarations of Dr. Leonore C. Witchey-Lakshmanan (ECF No. 13-7), Dr. Jeffrey N. Clark (ECF No. 13-10), Dr. Michael K. Rust (ECF No. 13-14), Dr. Dallas E. Johnson (ECF No. 13-15), Dr. Wesley L. Shoop (ECF No. 11-3), Dr. Robert M. Hamer (ECF No. 11-12), Donald Schwartz (ECF No. 13-9 at 9-12) and Elizabeth C. Murphy (ECF No. 20-1). The declaration testimony and accompanying exhibits are part of the preliminary injunction hearing record. In addition, the parties stipulated that testimony and exhibits received into evidence in connection with the hearings held in *BASF Agro B.V. v. Cipla Ltd.*, No. 3:07-CV-125 (CDL) (M.D. Ga.) on May 16-17, 2011, June 8, 2011 and May 21-23, 2012 would be deemed part of the record for purposes of the preliminary injunction motion. Stipulation, June 19, 2012, ECF No. 14.

II. Merial's Likelihood of Success on the Merits

To prevail on its preliminary injunction motion, Merial must establish a likelihood of success on the merits. This means that Merial "must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). If Velcera "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that [Merial] cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001). Where, as here, the alleged infringer launches "an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial." *Titan Tire Corp.*, 566 F.3d at 1377. "The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence[.]" *Id.* "While the evidentiary burdens at the preliminary injunction stage track the burdens at trial, importantly the ultimate question before the trial court is different." *Id.* At this stage in the litigation, Velcera does not have to persuade the Court that the '329 Patent is invalid; rather, Merial must show the Court "that, despite the challenge

presented to validity, [Merial] nevertheless is likely to succeed at trial on the validity issue." *Id.*; *accord Altanta Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1006 (Fed. Cir. 2009).

In support of its contention that it is likely to show at trial that 2012 PetArmor Plus infringes its '329 Patent, Merial first argues that based on the Court's prior findings in the contempt proceeding, Velcera is collaterally estopped from asserting that 2012 PetArmor Plus does not infringe the '329 Patent. Alternatively, Merial asserts that even if Velcera is not collaterally estopped from asserting non-infringement, Merial is likely to show that 2012 PetArmor Plus infringes the '329 Patent and that Merial will likely withstand Velcera's challenges to the validity of the '329 Patent. Velcera responds that collateral estoppel does not apply, that the '329 Patent is invalid and that 2012 PetArmor Plus does not infringe the '329 Patent. As discussed in more detail below, the Court rejects Merial's collateral estoppel argument, but the Court finds that Velcera has not raised a substantial question concerning either infringement or validity.

A. Collateral Estoppel

Merial argues that Velcera is collaterally estopped from asserting that 2012 PetArmor Plus does not infringe at least one claim of the '329 Patent based on the Court's finding in the

prior contempt proceeding that 2011 PetArmor Plus infringed the '329 Patent. Specifically, Merial maintains that Velcera is collaterally estopped from contesting Merial's contention that the active ingredient concentrations of 9.8% fipronil and 8.8% methoprene contained in 2012 PetArmor Plus for Dogs and 9.8% fipronil and 11.8% methoprene contained in 2012 PetArmor Plus for Cats constitute "synergistic effective amounts" of the active ingredients and that 2012 PetArmor Plus formulation includes at least one customary spot-one adjuvant.

For collateral estoppel to apply, Merial must establish the following:

> "(1) the issue at stake was identical to the one involved in the prior litigation; (2) the issue had been actually litigated in the prior suit; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding."

Bayer AG v. Biovail Corp., 279 F.3d 1340, 1345 (Fed. Cir. 2002) (quoting *In re McWhorter*, 887 F.2d 1564, 1566 (11th Cir. 1989) (per curiam)); *see also id.* (noting that "[b]ecause the application of collateral estoppel is not a matter within the exclusive jurisdiction of [the Federal Circuit, the Federal Circuit] applies the law of the circuit in which the district court sits, the Eleventh Circuit in this case.") (internal citation omitted).

Although the Court did determine in the prior contempt proceeding, in which Velcera was a party, that the active ingredient concentrations of 9.8% fipronil and 8.8% methoprene contained in 2011 PetArmor Plus for Dogs and 9.8% fipronil and 11.8% methoprene contained in 2011 PetArmor Plus for Cats are synergistic effective amounts of the active ingredients, that determination was based, at least in part, on factual findings that were established due to Cipla's default. *See 2011 Contempt Order*, 2011 WL 2489753, at *11 (noting that Cipla's product, Protektor Plus, contained "9.7% fipronil liquid and 11.8% methoprene" and that the "percentages admittedly, by virtue of the default, existed in 'synergistic' amounts."). Since Velcera, as an intervenor in the contempt action, had to accept the facts established by Cipla's default in that proceeding, it never had the opportunity to fully litigate those issues. *See Fed. Cir. Op.*, 2012 WL 1948879, at *12 (rejecting Velcera's argument that it did not have a full and fair opportunity to contest invalidity or infringement of the original product in the *contempt proceeding* because "Velcera, as an unsolicited intervenor in this action, joined subject to all prior determinations of fact and law that preceded its intervention" and recognizing that "*for purposes of this litigation*, the 2008 default judgment against Cipla established, among other things, that the '329 patent was not invalid and was infringed by

Cipla's Protektor Plus product"). Although Velcera was stuck with those default admissions in the contempt proceeding, they do not follow Velcera to this new infringement action. Thus, Velcera is not collaterally estopped from contesting any of the elements of infringement in this action, including the issues of whether the active ingredients exist in synergistic effective amounts and whether its 2012 PetArmor Plus products contain at least one customary spot-on adjuvant.

B. Validity of '329 Patent

The Court must next determine whether Merial is likely to withstand Velcera's challenges to the validity of the '329 Patent. Velcera asserts that Merial cannot establish a likelihood of success on the merits because the '329 Patent is invalid under 35 U.S.C. § 112 ("§ 112") and 35 U.S.C. § 103(a) ("§ 103(a)") for four reasons: (1) the '329 Patent is not enabling (§ 112), (2) the '329 Patent does not contain an adequate written description (§ 112), (3) the '329 Patent is invalid due to indefinite claims (§ 112), and (4) the '329 Patent is invalid for obviousness based upon prior art (§ 103(a)).

As a preliminary matter, the Court notes that the '329 Patent is entitled to a presumption of validity because patents are presumed to be valid, 35 U.S.C. § 282, and because the '329 Patent was confirmed pursuant to a reexamination proceeding.

See Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1342 (Fed. Cir. 2003) (finding, based on the presumption of validity and the fact that the patent had been subjected to reexamination, that the patentee had established that it was reasonably likely to withstand a validity challenge). Though the confirmation following reexamination is not dispositive of the '329 Patent's validity, the fact that it was issued and then confirmed pursuant to a reexamination proceeding does suggest that the '329 Patent is not invalid due to obviousness and that the '329 Patent satisfies § 112's requirements of enablement, written description and definite claims. Even without this presumption of validity, the Court concludes, as explained in more detail in the following discussion, that Merial has carried its burden of showing that Velcera's invalidity defenses lack substantial merit for purposes of preliminary injunctive relief. *See Titan Tire Corp.*, 566 F.3d at 1377 (discussing alleged infringer's burden to establish a substantial question of validity and patentee's burden to establish that the invalidity defense lacks substantial merit).

1. Enablement Requirement

"The first paragraph of 35 U.S.C. § 112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention." *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988). "To be enabling, the

specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003) (internal quotation marks omitted). In other words, the "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988); *accord In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009). "Enablement is determined as of the effective filing date of the patent's application." *In re '318 Patent Infringement Litig.*, 583 F.3d at 1323.

In this action, Velcera contends that the specification of the '329 Patent does not teach a person of ordinary skill in the art to make or use the invention, a composition containing synergistic amounts of fipronil and methoprene, without undue experimentation. The Court notes that "[e]nablement is not precluded by the necessity for some experimentation." *In re Wands*, 858 F.2d at 736. The key question is whether the experimentation needed to practice the invention is undue. *Id.* at 737. "Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1)

the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

To evaluate enablement, as well as the other invalidity defenses, the parties rely on expert testimony from witnesses they contend are persons of ordinary skill in the art. The Court finds that two of Merial's experts, Drs. Witchey and Clark, are exceptionally well qualified to opine about the '329 Patent as persons of ordinary skill in the art. Dr. Witchey is a pharmaceutical product formulator with impeccable credentials that include both educational and practical experience qualifications. She is a chemical engineer with a Bachelor of Science and a Master of Science in chemical engineering from The Ohio State University and a Ph.D. in chemical engineering from North Carolina State University. Dr. Witchey has more than twenty years of experience in pharmaceutical product development, including ten years of researching and developing formulations of animal health care products, with particular emphasis in ecto- and endo-parasitic control. Dr. Clark is also exceptionally well qualified in the area of animal health product formulation and development, including the use of

chemical parasiticides to combat fleas and ticks in dogs and cats. Dr. Clark has a Bachelor of Science in biochemistry from the University of Massachusetts, a Ph.D. in biochemistry from the Massachusetts Institute of Technology, and a Doctor of Veterinary Medicine from the University of Tennessee-Knoxville. He has more than thirty years of experience in animal and human health pharmaceutical product discovery and development, including more than twenty-five years in animal health product development with a focus on parasite control using novel chemotherapeutic agents.

In addition to their impressive curricula vitae, the Court was persuaded by the live testimony of Drs. Witchey and Clark, including their manner of testifying, their demeanor, and their grasp of the issues. The Court found them to be refreshingly candid scientists attempting to educate the Court and not simply retained expert witness advocates. The Court also finds that their testimony was essentially unimpeached. On the other hand, Velcera's ordinary skill in the art expert did not match Drs. Witchey and Clark in qualifications or persuasiveness. Although the Court found him to be a qualified parasitologist, his credentials do not match those of Drs. Witchey and Clark insofar as the issues in this patent litigation are concerned. This became particularly clear when he was effectively impeached through the use of a patent which he authored. That patent was

broader, more indefinite, and less enabling than the '329 Patent, yet Velcera's expert criticized the '329 Patent for deficiencies that were glaringly more pervasive in the patent which he authored.

Based on the testimony of Drs. Witchey and Clark, the Court is satisfied that Merial is likely to succeed in establishing that the '329 Patent meets the enablement requirement and teaches a person of ordinary skill in the art to make or use the invention without undue experimentation. The '329 Patent is primarily a formulation patent. According to Dr. Witchey, the expert formulator, the '329 Patent gives very specific guidance in terms of practicing the patent to develop a composition containing synergistic amounts of fipronil and methoprene. Based on her expertise and her reading of the '329 Patent, Dr. Witchey testified that it would take a person of ordinary skill in the art a few days or a couple of weeks to develop a handful of formulations to be handed off to a parasitologist for further testing. Furthermore, Dr. Clark testified that, based on the teachings of the '329 Patent, it would take a person of ordinary skill in the art no more than five or six months from start to finish to develop an embodiment of the '329 Patent. In contrast, Dr. Clark testified that without the '329 Patent, it would be a major research project to develop such a product, taking a person of ordinary skill in the art several years.

Based on all of this evidence, the Court is satisfied that Merial is likely to withstand Velcera's challenge to enablement by establishing that the '329 Patent teaches a person of ordinary skill in the art to make or use the invention, a composition containing synergistic amounts of fipronil and methoprene, without undue experimentation.

2. Written Description Requirement

Section 112 also requires that a patent specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112. The written description "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (alteration in original) (internal quotation marks omitted). "The test is whether the disclosure 'conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (quoting *Ariad*, 598 F.3d at 1351). While a mere wish or plan to obtain the claimed invention is not sufficient to meet the written disclosure

requirement, "the written description requirement 'does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.'" *Id.* (quoting *Ariad*, 598 F.3d at 1352.

Velcera contends that the '329 Patent has a deficient written description because, although it states that the invention relates to a novel composition to control fleas on cats and dogs "based on a synergistic combination of parasiticides," Prelim. Inj. Hr'g Ex. PX-700, United States Patent No. 6,096,329 col. 1 l. 10-11, ECF No. 31-15 ("'329 Patent"), the patent did not disclose any testing for synergy and did not disclose a synergistic compound. Velcera asserts that the '329 Patent merely recites "a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention." *Ariad*, 598 F.3d at 1353.

The Federal Circuit has "made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention

can satisfy the written description requirement." *Id.* at 1352. A specification that describes an invention in terms of ranges does not fail the written description requirement as long as the claimed composition is selected from ranges disclosed in the written description and as long as the written description is sufficient to show a person of ordinary skill in the art that the inventor possessed the claimed composition as of the filing date. *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000).

According to Drs. Witchey and Clark, the specification of the '329 Patent discloses explicitly identified compounds (fipronil and methoprene), as well as a solution to the problem (fipronil and methoprene in synergistic amounts). The '329 Patent teaches that fipronil and methoprene can be used together, that they can translocate and that they are synergistic. While the specification does not describe the exact composition claimed, the specification discloses a specific combination of active ingredients, ratios and concentrations of the active ingredients, a limited selection of adjuvants, preferred embodiments and dosage amounts. The types of prophetic examples disclosed in the '329 Patent "are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement," *Ariad*, 598 F.3d at 1357, so long as there is evidence that a

person of ordinary skill in the art would be able to identify the chemical composition based on the specification's functional description. *See id.* at 1354 (noting that the Federal Circuit in *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) held a patent invalid because the patentee did not present any evidence that a person of ordinary skill in the art would be able to identify any compound based on the specification's vague description). Based on the testimony of Drs. Witchey and Clark, the Court is satisfied that Merial will likely succeed in showing that the written description of the '329 Patent is sufficient to show a person of ordinary skill in the art that the inventor possessed the claimed composition as of the filing date. Therefore, the Court concludes that Merial is likely to withstand Velcera's written description challenge.

3. Definiteness Requirement

In addition to the enablement and written description requirements, § 112 requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. The purpose of the definiteness requirement is to "inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

"Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims." *Id.* A claim is invalid as indefinite under § 112 if the claim is not amenable to construction. *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338 (Fed. Cir. 2003). "Because a claim is presumed valid, a claim is indefinite only if the claim is insolubly ambiguous, and no narrowing construction can properly be adopted." *Id.* at 1338-39 (internal quotation marks omitted). In addition, "[a] claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

Velcera contends that the '329 Patent does not provide a person of ordinary skill in the art with enough information to determine which spot-on compositions with fipronil and methoprene are synergistic and thus infringing. One of Velcera's arguments raises concerns with the tests Merial proffered in support of its assertion that Frontline Plus is an embodiment of the '329 Patent that contains synergistic amounts of fipronil and methoprene. According to Velcera, those tests did not show synergy at all tested time points, so a composition may fall outside the claim scope depending on the test method. The Federal Circuit rejected a similar argument in *Geneva*

Pharmaceuticals, finding that the term "synergistically effective amount" is a functional limitation that encompasses dosages that yield synergy and that "once a particular amount yields synergy under any circumstance, that amount is 'synergistically effective.'" *Geneva Pharm.*, 349 F.3d at 1384 (finding that patent was not invalid for indefiniteness but was invalid for "nonstatutory double patenting").

Velcera further asserts that the '329 Patent does not provide an indication of the type of testing to determine whether a given composition is synergistic. Velcera acknowledges, however, that there are a number of ways to test for synergy. Moreover, the testimony of Drs. Witchey and Clark establishes that a person of ordinary skill in the art would know how to conduct tests to determine whether a composition has synergistic amounts of fipronil and methoprene. Therefore, Merial is likely to establish that the '329 Patent is clear enough that a person of ordinary skill in the art could determine whether a particular composition of fipronil and methoprene is synergistic and thus infringes the '329 Patent. For these reasons, the Court finds that Merial is likely to withstand Velcera's challenge to definiteness.

4. Non-Obviousness Requirement

Velcera contends that even if the '329 Patent satisfies the § 112 requirements, the patent is invalid for obviousness. A

patent is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). In determining obviousness, the courts consider (1) "the scope and content of the prior art", (2) "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art" and (4) objective evidence of nonobviounsess. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). Objective evidence of nonobviousness includes such "secondary considerations as commercial success, long felt but unsolved needs, [and] failure of others." *Id.* at 17.

In support of its assertion that the '329 Patent is invalid for obviousness, Velcera points to two published patents: U.S. Patent No. 5,597,429 ("Senbo Patent") and U.S. Patent No. 5,236,934 ("Gladney Patent"). It is significant that the U.S. Patent and Trademark Office ("USPTO") considered the Senbo Patent during the initial prosecution of the '329 Patent and also during the reexamination because it is "especially difficult" for an alleged infringer to show invalidity for obviousness when the alleged infringer "attempts to rely on prior art that was before the patent examiner during

prosecution." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004).

Velcera contends that the Senbo Patent teaches "nearly every element of the claims" of the '329 Patent except the spot-on composition and that Gladney discloses a spot-on composition, so the two references together disclose every component of the asserted claims, *except synergy*. As Velcera concedes, the Senbo Patent does not teach or mention spot-on compositions, and it does not disclose a composition where the active ingredients are present in synergistic effective amounts. Moreover, based on the evidence presented to the Court, including the testimony of Dr. Witchey, the Senbo Patent does not teach a person of ordinary skill in the art how to produce an effective (or synergistic) formulation of fipronil and methoprene that could be applied as a spot-on treatment and distributed around an animal's body through translocation.

Though the Gladney Patent offers the idea for a spot-on treatment, it teaches a locally-applied formulation of a high concentration of a pyrethroid for treatment of ecto-parasites, such as fleas, on mammals. Based on the evidence presented to the Court, including the testimony of Dr. Witchey, the Gladney patent does not teach a person of ordinary skill in the art to try fipronil and methoprene together in a spot-on composition in synergistic amounts or otherwise. In fact, according to Dr.

Witchey, based on the properties of pyrethroids compared to the properties of fipronil and the fact that the Gladney Patent teaches that translocation is achieved through a relatively high concentration of a pyrethroid, the Gladney Patent actually teaches away from attempting a spot-on composition using fipronil.

For all of these reasons, the Court finds that the Senbo Patent and the Gladney Patent do not indicate that a person of ordinary skill in the art would have perceived a reasonable expectation of success in terms of formulating an efficacious spot-on composition using fipronil and methoprene. Thus, the Senbo Patent and the Gladney Patent do not render obvious the teachings of the '329 Patent.

As part of the obviousness analysis, the Court must also consider secondary considerations of nonobviousness. *E.g.*, *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1343 (Fed. Cir. 2010). "Such evidence may often establish that an invention appearing to have been obvious in light of the prior art was not." *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012) (internal quotation marks omitted). "These objective criteria thus help turn back the clock and place the claims in the context that led to their invention." *Id.* Relevant secondary considerations of nonobviousness include unexpected results, copying, commercial success, praise by others, and

long-felt need. *Id.* at 1379. Velcera cannot seriously dispute that Merial's Frontline Plus products, which embody the '329 Patent as discussed in more detail below, have enjoyed tremendous commercial success due to the combination of fipronil and methoprene compared with fipronil-only products, have been copied by others, and have received significant industry praise. Velcera also cannot seriously dispute that the Frontline Plus products met a long-felt industry need for a product that is efficacious against ticks and against fleas in both their larval and adult forms, is easy to apply, does not wash off, and is long lasting. The Court is therefore persuaded that Merial has offered significant objective evidence of nonobviousness.

For all of these reasons, the Court concludes that Merial has established that it will likely withstand Velcera's obviousness challenge to the '329 Patent.

5. Conclusion Regarding Validity

For the reasons set forth above, the Court finds that Merial has shown that it will likely withstand Velcera's invalidity challenges to the '329 Patent.

C. Infringement of '329 Patent

The Court now turns to the question whether Merial has established that it is likely to succeed on the merits of its infringement claim. To meet this burden, Merial must demonstrate that it is likely to show that 2012 PetArmor Plus

infringes at least one claim of the '329 Patent. Merial contends that 2012 PetArmor Plus infringes at least one or more of Claims 4, 26, 77 and 85 of the '329 Patent and that Velcera will induce infringement of at least one or more of Claims 101, 106, 107 and 108 of the '329 Patent. A determination of patent infringement requires the Court to determine the scope and meaning of the patent's claims and then compare the claims to the allegedly infringing product. *E.g., PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1357 (Fed. Cir. 2004). For purposes of this Order, the Court focuses on Claim 4, which was the main claim addressed during the preliminary injunction hearing.

Claim 4 of the '329 Patent is a dependent claim of Claim 1. Claim 1 of the '329 Patent requires three elements to infringe: (1) a "synergistic effective amount[]" of fipronil, (2) a "synergistic amount of a compound which mimics juvenile hormones," and (3) "at least one customary spot-on formulation adjuvant." '329 Patent col. 10 l. 11-15. Claim 4 limits "the compound which mimics juvenile hormones" to methoprene. *Id.* col. 10 l. 26-28. Thus, Claim 4 of the '329 Patent requires a "synergistic spot-on composition" that contains "synergistic effective amounts" or "synergistic amounts" of fipronil and methoprene. Therefore, to establish infringement, Merial must show that 2012 PetArmor Plus contains synergistic amounts of

fipronil and methoprene, as well as at least one spot-on adjuvant. At this stage in the litigation, Velcera does not dispute that 2012 PetArmor Plus contains fipronil, methoprene and at least one spot-on adjuvant. Velcera's challenge to infringement depends upon whether 2012 PetArmor Plus (or Frontline Plus, for that matter) contains *synergistic* amounts of fipronil and methoprene.

The parties do not appear to have a serious dispute as to the meaning of "synergistic amounts" for purposes of the preliminary injunction motion. Based on the plain meaning of the term "synergistic," for purposes of this Order, the Court finds that the term "synergistic amounts" means amounts that yield synergistic effects and that "synergistic" means greater than the expected additive effect. In other words, "synergistic" means that the combination of fipronil and methoprene achieves improved results relative to the additive results when the agents are administered independently. The parties' chief disagreement relates to whether the products at issue in this action actually contain synergistic amounts of fipronil and methoprene.

To establish that 2012 PetArmor Plus infringes the '329 Patent, Merial must show that 2012 PetArmor Plus contains synergistic amounts of fipronil and methoprene. It is undisputed that Merial has not tested 2012 PetArmor Plus.

Rather, Merial argues that for purposes of evaluating whether fipronil and methoprene exist in synergistic effective amounts, 2012 PetArmor Plus has the same synergistic effective amounts of fipronil and methoprene as 2011 PetArmor Plus and that 2011 PetArmor Plus has the same synergistic effective amounts of fipronil and methoprene as Frontline Plus. Merial asserts that Frontline Plus is an embodiment of the '329 Patent that was designed and manufactured based on the teachings of the '329 Patent, which included the Declaration and synergy studies of Dr. Alan Marchiondo as part of the patent history. According to Merial, Frontline Plus has the same synergistic effective amounts of fipronil and methoprene that the studies of Dr. Marchiondo showed were synergistically effective. Therefore, according to Merial, the Marchiondo studies showing synergy support a finding that such synergy exists in 2012 PetArmor Plus. Velcera argues that 2012 PetArmor Plus is a different formulation from Frontline Plus, and therefore, Merial's deductive reasoning is flawed. More significantly, Velcera maintains that the Marchiondo studies are flawed and do not show synergy. The Court first addresses the Marchiondo studies and then turns to the differences between 2012 PetArmor Plus and Frontline Plus.

In the Marchiondo Declaration, Dr. Alan Marchiondo, a parasitologist who worked for Merial, reported to the USPTO that

studies conducted under his supervision showed that certain fipronil/methoprene compositions yielded synergistic results and that the fipronil/methoprene compositions were "surprisingly more ovicidally active for an extended period than composition[s] comprising just fipronil or (S)-methoprene alone." Prelim. Inj. Hr'g Ex. PX-716, Marchiondo Decl. ¶ 8(A) & (B), ECF No. 31-17. It is undisputed that the Marchiondo Declaration summarized *in vivo* studies on dogs and cats, among other studies. It is also undisputed that the *in vivo* dog study tested the efficacy of 10% fipronil and 9% methoprene alone and in combination and that the *in vivo* cat study tested the efficacy of 10% fipronil and 12% methoprene alone and in combination. The results of the *in vivo* dog study, which found a synergistic effect due to the combination of 10% fipronil and 9% methoprene, were peer reviewed and published by D.R. Young *et al.* in the Veterinary Parasitology Journal ("Young Article"). The question for the Court is whether the Marchiondo Declaration and the underlying studies reasonably establish that a composition of fipronil and methoprene in these amounts is synergistic.

Dr. Witchey and Dr. Clark, two distinguished persons of ordinary skill in the art with exceptional qualifications and extensive relevant experience, reviewed the Marchiondo Declaration and the underlying studies, as well as the Young

Article. They concluded that the research methodology is standard for this type of parasiticide test and that the studies were run using good laboratory practices and a sufficient number of animals and data points. There was also testimony that Dr. Marchiondo is a very well respected parasitologist and that the studies summarized in his Declaration had a level of reproducibility that is indicative of reliability. The Young Article was peer reviewed and published, which gives it another indicia of reliability. Drs. Witchey and Clark testified that the data in the Marchiondo declaration and underlying studies supports Dr. Marchiondo's conclusions of synergy, and Merial's statistical expert, Dr. Dallas Johnson, reviewed the data and concurred that it supported a conclusion of synergy.

Velcera's statistical expert, Dr. Robert Hamer, whom the Court found to be well qualified, criticized the statistical analysis in the Marchiondo Declaration and the Young Article, but he did not opine that no synergy exists. While Dr. Hamer's criticisms do raise legitimate concerns and cause some pause by the factfinder, the Court notes that Merial's burden is not to prove the elements of its claim at this stage of the proceedings with the precise exactitude typically expected of a Ph.D. statistician; rather, Merial's burden is to prove that it is likely to prove its claims at trial.

The Court also observes that statistical and scientific evidence is not the only evidence on this issue. Previous admissions by Velcera's Chief Executive Officer, Dennis Steadman, also support the conclusion that Marchiondo's studies show synergy and that the amounts of fipronil and methoprene in Frontline Plus and in the PetArmor Plus products exist in synergistic effective amounts. Mr. Steadman previously admitted that if the '329 Patent is valid, then the 2011 version of PetArmor Plus infringes it. *E.g.*, *Fed. Cir. Op.*, 2012 WL 1948879, at *14 (Fed. Cir. May 31, 2012). For 2011 PetArmor Plus to infringe the '329 Patent, then it must have fipronil and methoprene in synergistic amounts; therefore, Mr. Steadman's admission is not just an admission of infringement but is implicitly an admission that 2011 PetArmor Plus contained fipronil and methoprene in synergistic effective amounts.

This admission also corroborates the Marchiondo studies. It is undisputed that 2011 PetArmor Plus contained the exact same concentration of active ingredients as Frontline Plus: 9.8% fipronil and 8.8% methoprene in PetArmor Plus and Frontline Plus for Dogs and 9.8% fipronil and 11.8% methoprene in PetArmor Plus and Frontline Plus for Cats. Furthermore, there is no material difference in the amounts of fipronil and methoprene in Frontline Plus compared to the amounts Marchiondo found to be synergistically effective. The Marchiondo Declaration and the

underlying studies support the conclusion that fipronil and methoprene are in synergistic effective amounts when the composition for use on cats contains 10% fipronil and 12% methoprene and the composition for dogs contains 10% fipronil and 9% methoprene. As previously noted, the Frontline Plus products contain active ingredient concentrations that are nearly identical to the concentrations discussed in the Marchiondo Declaration and the underlying studies: Frontline Plus for Dogs contains 9.8% fipronil and 8.8% methoprene, and Frontline Plus for Cats contains 9.8% fipronil and 11.8% methoprene. According to Dr. Witchey, the difference of 0.2% between the active ingredient concentrations tested by Marchiondo and the active ingredient concentrations in the Frontline Plus products would not make a difference in terms of synergistic efficacy. Therefore, Merial is likely to show that 2011 PetArmor Plus contains fipronil and methoprene in synergistically effective amounts.

The Court must next determine whether Merial is likely to show that 2012 PetArmor Plus likewise contains fipronil and methoprene in synergistic amounts. As discussed above, PetArmor Plus was recently reformulated. 2012 PetArmor Plus contains the exact same active ingredient formulation as Frontline Plus and the 2011 version of PetArmor Plus: 9.8% fipronil and 8.8% methoprene in PetArmor Plus for Dogs and 9.8% fipronil and 11.8%

methoprene in PetArmor Plus for Cats. The difference between 2012 PetArmor Plus and 2011 PetArmor Plus is that the 2011 version contained two inert ingredients that the current version does not, and the volume of those ingredients was replaced with an increase in volume of another inert ingredient. Specifically, in the 2012 formulation of PetArmor Plus, the crystallization inhibitors that were present in the 2011 version have been removed and replaced with an increased volume of Transcutol P. According to Velcera, this modification changed the delivery mechanism for the active ingredients. There is persuasive evidence, however, that the change to the inactive ingredients does not have a material effect on the synergy of fipronil and methoprene. In seeking approval for the 2012 version of PetArmor Plus, Velcera represented to the U.S. Environmental Protection Agency that the change to the inactive ingredients was merely a minor formulation change. Furthermore, Dr. David M. Petrick, Velcera's Executive Vice President of Research and Development and Regulatory Affairs, previously testified that Velcera had tested 2012 PetArmor Plus and confirmed that the formulation change to the inactive ingredients did not "negatively impact either product efficacy or overall aesthetics." Prelim. Inj. Hr'g Ex. PX-755, Petrick Decl. ¶ 19, ECF No. 31-28. According to Dr. Witchey, because 2012 PetArmor Plus is as efficacious as the 2011 version, the

minor formulation change to the inactive ingredients did not affect the synergy of the active ingredients. Based on this evidence, the Court finds that Merial is likely to succeed in showing that 2012 PetArmor Plus contains synergistic amounts of fipronil and methoprene plus at least one spot-on adjuvant, which means that Merial is likely to show that PetArmor Plus infringes at least Claim 4 of the '329 Patent. Accordingly, the Court concludes that Merial is likely to succeed on the merits of its infringement claim.

III. Other Preliminary Injunction Elements

Having found that Merial is likely to withstand Velcera's challenges to the validity of the '329 Patent and is likely to succeed on the merits of its infringement claim, the Court must address the remaining preliminary injunction factors. Thus, the Court must determine whether Merial has established that it is likely to suffer irreparable harm in the absence of preliminary injunctive relief, that the balance of equities tips in its favor and that an injunction is in the public interest.

The Court finds that Merial has demonstrated that Velcera's planned sale of 2012 PetArmor Plus will irreparably injure Merial by causing Merial to lose market share. The Court previously found that Velcera's 2011 launch of PetArmor Plus resulted in an irreparable injury to Merial. *2011 Contempt Order*, 2011 WL 2489753, at *15. The Court concluded that the

introduction of a generic fipronil and methoprene product like PetArmor Plus would result in considerable loss of market share to Merial and that Velcera's marketing strategy specifically targeted Frontline Plus, touting that PetArmor Plus is exactly like Frontline Plus but less expensive. *Id.* The Court further found that there is not an adequate remedy at law for injuries such as loss of market share and brand recognition. *Id.*

The Court also heard testimony in the context of this year's contempt action that the 2011 launch of 2011 PetArmor Plus caused a loss of Merial's market share for Frontline Plus, caused price erosion effects to Frontline Plus and negatively impacted veterinarians' attitudes toward Frontline Plus, thus reducing the likelihood that they would recommend Frontline Plus for their patients. With regard to the planned 2012 launch of PetArmor Plus, there is evidence that Velcera's marketing strategy for 2012 PetArmor Plus includes plans to continue targeting Frontline Plus. Based on the adverse effects to Merial due to the 2011 launch of PetArmor Plus and Velcera's plan to continue targeting Frontline Plus, the Court concludes that if the 2012 launch of 2012 PetArmor Plus is not enjoined, Merial is likely to suffer adverse effects similar to those it suffered in 2011, including loss of market share, price erosion and loss of recommendations from veterinarians. For these reasons, the Court finds that Merial will suffer irreparable

harm if Velcera is not enjoined from selling 2012 PetArmor Plus, so this factor weighs in favor of a preliminary injunction.

The balance of hardships also weighs in favor of a preliminary injunction. Merial's interest in enforcing its patent rights is strong. Though Velcera argues that an injunction requiring Velcera to stop its launch plans would harm Velcera financially, as the Federal Circuit has noted, "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008). Moreover, the Court notes that 2012 PetArmor Plus is not yet on the market, and enjoining the launch of the product would be far less burdensome than enjoining sales of a product that is already on the market. Finally, the Court has set an expedited trial date for November of this year, so the length of the preliminary injunction is likely limited to five months. For all of these reasons, the balance of hardships supports the issuance of a preliminary injunction.

The final question is whether the public interest weighs in favor of a preliminary injunction. As the Court has previously observed, even though "the public may benefit from a lower priced fipronil/methoprene product if . . . Velcera were allowed to" sell PetArmor Plus, "the public is also served by enforced

compliance with . . . the United States patent laws." *2011 Contempt Order*, 2011 WL 2489753, at *16. The Court thus finds that the public interest factor weighs in favor of a preliminary injunction.

PRELIMINARY INJUNCTION

Based on the foregoing findings of fact and conclusions of law, Merial's Motion for Preliminary Injunction (ECF No. 5) is granted and the Court issues the following preliminary injunction: Until further order of the Court, Velcera Inc. and FidoPharm Inc., as well as those acting in concert with either of them and who have knowledge of this Order, are hereby enjoined from making, using, offering for sale, selling, causing to be sold, or otherwise launching in the United States, Velcera's 2012 PetArmor Plus products, LC-2010-3 Fipronil and S-Methoprene for Cats (PetArmor Plus for Cats) and LC-2010-4 Fipronil and S-Methoprene for Dogs (PetArmor Plus for Dogs).

SECURITY

Federal Rule of Civil Procedure 65 provides that a preliminary injunction may be issued "only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). The parties stipulated prior to trial that the issue regarding the amount and nature of any security would be addressed after the

Court issued its ruling on the motion for preliminary injunction. Therefore, the Court finds that the preliminary injunction is effective today, and the parties shall address the security issue as follows. Within fourteen days of today's Order, Velcera shall file a motion for security setting out what it seeks as reasonable security and the basis for its request. Merial shall file a response to that motion within fourteen days of being served with that motion. The Court will then decide the appropriate nature and amount of security to be given.

IT IS SO ORDERED, this 29th day of June, 2012.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE